

Atty Dkt. No.: LIFE033  
USSN: 10/052,212

### REMARKS

#### Formal Matters

Claims 97-108, 111-113, 115-125, 133-136, 138, 140-142 are pending in the application after entry of the amendments set-forth herein.

Claim 97 has been amended to specify that the device includes a sealing ridge and mateable sealing groove. Support for this amendment may be found in the originally filed claims and the specification, e.g., at paragraphs 0087-0089 and claims 109-110.

Claims 113 and 133 have been amended to clarify that the base includes an opening that is permissive of only a single test strip at a time. Support for this amendment may be found in the specification and the originally filed claims, e.g., at paragraphs 73, 93, originally filed claims 113 and 133, and Figs. 7 and 7A.

Claim 138 has been amended to replace the instructions for using the at least one device with the subject matter of claim 139, i.e., at least one test strip, and claim 139 has been cancelled. Claims 140 and 141 have been amended to now depend from claim 138.

Claim 135 has been amended to clarify the claimed invention by specifying that the advancing is accomplished with an automated advancing means. Support for this amendment may be found in the specification, e.g., at paragraph 79.

Claims 109, 110, 139, 143 and 144 have been canceled and claims 126-132 and 137 are withdrawn as being directed to non-elected subject matter.

Claims 98, 99, 101, 104 and 106, have been amended to further clarify the invention by specifying that the test strips recited in the claims are with respect to test strips when stored in the device and claims 107 and 108 have been amended to remove reference to test strips and to specify a test strip segregation means. Support for this amendment may be found in the specification and the originally filed claims, e.g., at paragraphs 71 and 99.

Applicants have also corrected the status of claims 100, 102, 103, 105, 109-112, 116-125, 134 and 136 which had been incorrectly identified as original claims in Applicants' previous communication dated March 11, 2004, which was responsive to the office action dated December 16, 2003. These claims were added as new claims in a preliminary amendment dated March 14, 2002 in which all of the original claims were cancelled. However, in Applicants' previous communication dated March 11, 2004,

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these claims, as well as other claims, were inadvertently identified as original claims. The Applicants apologize for this error and note that the error was made inadvertently.

No new matter is added. Accordingly, the Applicants respectfully request entry of the amendments.

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow claims 97-108, 111-113, 115-125, 138, 140-142.

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**REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 98-112, 143 and 135 have been rejected under 35 USC §112, second paragraph.

Claims 98-112 have been rejected for assertedly failing to further limit claim 97 because test strips have not been positively claimed. As described above, claims 98, 99, 101, 104 and 106 have been amended to further clarify the invention by specifying that the test strips recited in the claims are with respect to test strips *when* stored in the device and claims 107 and 108 have been amended to remove reference to test strips and to specify a test strip segregation means. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

The Examiner has rejected claim 135 and asserts that it is not clear how the step is accomplished automatically. This claim has been amended to specify automated means, which clarifies how the step is accomplished automatically. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

The Examiner has rejected claim 143 and asserts that it is not clear what type of element is intended for obtaining the sample. This claim has been cancelled. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

**REJECTION UNDER 35 U.S.C. §102(b)**

Claims 97-98, 101-103, 107-113, 115, 118-121, 124, 133-136 have been rejected under 35 USC §102(b) as being anticipated by Eikmeier, et al. (US 5,505,308). Claims 109 and 110 have been cancelled.

As described above, independent claim 97, and claims 98, 101-103 and 107-112 that depend therefrom, have been amended to specify a surface having a sealing ridge and surface having a sealing groove mateable with the sealing ridge to provide a substantially air and moisture tight seal when the sealing ridge and said sealing groove are mated together.

Eikmeier et al. describes a base structure in the form of a holder 2 and a flap 5 for closing the base structure. Eikmeier et al. do not describe that any part of the device includes a sealing ridge and mateable sealing groove. In fact, none of the figures show any such sealing ridge and sealing groove and

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clearly show that the mating surfaces of the base structure and are flap are flat surfaces (see for example fig. 2, and figs. 3A, 3B and 3C). The Examiner points to col. 1, lines 66-col. 2 which describes that that the flap "presses onto the opening of the storage vessel...", but this description clearly does not describe any sealing ridge and mateable groove, especially in view of the figures that show flat surfaces.

Accordingly, for at least this reason, the cited reference does not anticipate claims 97, 98, 101-103 and 107-108, 111-112. As such, the Applicants respectfully request that this rejection be withdrawn.

Independent claim 113, and claims 115, 118-121 and 124 that depend therefrom, and independent claim 133, and claims 134-136 that depend therefrom, specify that the base includes an opening permissive of only a single test strip at a time. However, the opening of the base structure of Eikmeier et al. is clearly dimensioned to be permissive a plurality of test elements and in fact is shown in the figures as accommodating all of the multitude of test elements held in the base structure.

Furthermore with respect to the method claim of claim 133, Eikmeier et al. also fail to specify the step of positioning a single test strip at a time within the opening, as claimed in the subject claim, as the opening of the base structure of Eikmeier et al. is dimensioned to be permissive a plurality of test elements and in fact is shown accommodating all of the test elements held in the base structure, as described above.

Accordingly, for at least these reasons, the cited reference does not anticipate claims 97-98, 101-103, 107-108, 111-113, 115, 118-121, 124, 133-136. As such, the Applicants respectfully request that this rejection be withdrawn.

#### **REJECTION UNDER 35 U.S.C. §103(a)**

Claims 125 and 138-144 have been rejected under 35 USC §103(a) as being unpatentable over Eikmeier et al in view of Berke et al.

Claim 125 specifies that the device is configured for threadable engagement of the base and the cover of the device. The Examiner asserts that it would have been within the skill of the art to further modify Eikmeier et al. to include a threadable engagement. However, in order to modify the structure of Eikmeier et al. to accommodate a functioning threadable engagement of the base structure and the tab, one would have to completely re-configure the base structure and tab and disregard the described manner of engaging the base structure and tab together.

As is known to those of skill in the art, threadable engagements are only functionable with

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respect to cylindrically shaped structures. However, clearly Eikmeier et al. is not cylindrical and is clearly rectangular as shown in the figures. In fact, Eikmeier et al. clearly describe a "closed system in the form of an elongated box" (col. 3, lines 49-50). Still further, Eikmeier et al. describe ways of pressing or pulling the flap onto the opening of the base structure (e.g., spring, a rubber band or other reset devices) and which do not include a threadable engagement of any kind. (see for example figs. 2, 3A, 3B and 3C; col. 2, lines 8-38 and col. 4, lines 1-22). There would be no reason to use a threadable engagement in Eikmeier because other structures are used to hold the base and tab together (e.g., springs, rubber band, etc.). Accordingly, to modify the structure of Eikmeier et al. to include a threadable engagement would mean one would have to selectively disregard the teachings of Eikmeier et al. with respect to the described rectangular shape and with respect to the description of how the flap is held to the base structure and selectively adopt certain other teaching of Eikmeier et al. such as the general teaching of a base and a flap for closing the base. However, there is no motivation or suggestion for such selective adoption. As Berke et al. is cited solely for teaching a test kit, Berke et al. fail to make-up for the deficiencies of Eikmeier et al.

For at least the reasons described above, claim 125 is patentable over the cited references. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 138-144 specify a kit that includes at least one device according to one of claim 97 and claim 113 and at least one test strip. As noted above, claims 139 and 143-144 have been cancelled. As described above, Eikmeier et al. fail to teach or suggest a device as claimed in claims 97 and 113 and Berke et al. fails to make up for the deficiencies of Eikmeier et al. Accordingly, claims 138, 140 and 141 are patentable over the cited references. As such, the Applicants respectfully request that this rejection be withdrawn.

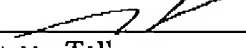
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**Conclusion**

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance. The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, Order No. LIFE033.

Respectfully submitted,  
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Date: 8/26/04

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